K012938 1/2

510(k) Summary
Image Guided Surgical Instruments
For Knee Applications

FEB 0 8 2002

Submitter's name: Smith & Nephew, Inc., Orthopaedic Division
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901-399-5007
Contact person: Trude C Naff
Date summary prepared: August 30, 2001
Trade or proprietary device name: Not determined

Common or usual name: Stereotactic Instrument

Classification name: Stereotactic Instrument

Device Class: Class II

Device Product Code: **HAW**

Panel Code: Neurology/84

Subject device description:

The Smith & Nephew Image Guided Instruments for Knee Applications are commercially available instruments that have been modified by incorporating a dovetail mount that will allow infrared LED (light emitting diodes) or passive markers image guided arrays to be fixed onto the instruments. This will allow the instruments to be tracked in real time in the surgical field.

B. ***Applicable 510(k)'s***

Manufacturer	*Submission Name*	*FDA Clearance Date*
Kinamed	Ortho Pilot	
Surgical Navigation Technologies	StealthStation	1-24-96
Surgical Navigation Technologies	StealthStation™ System Passive Instrument Option	9-16-97
Surgical Navigation Technologies	StealthStation™ System -ENT Application Addendum	1-21-98
Surgical Navigation Technologies	StealthStation® FluoroNav™ Module	4-22-99
Surgical Navigation Technologies	Indications Modifications for the StealthStation System	2-22-00
Surgical Navigation Technologies	StealthStation Generation 3	5-3-00

Subject device intended use:

Image Guided Surgical Instruments for Knee Applications are intended to assis the surgeon in precisely locating anatomical structures in either open or percutaneous procedures. ***Image Guided Surgical Instruments for Knee Applications*** are indicated for use in total knee procedures, including but not limited to, primary and revision total knee arthroplasty and unicompartmental knee arthroplasty, in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure. such as a long bone. can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

Technolocgical Characteristics:

Image Guided Surgical Instruments for Knee Applications are similar to currently legally marketed Class II stereotactic instruments in that they incorporate infrared LED (light emitting diodes) or passive markers onto the instruments that allow the instruments to be tracked in real time in the surgical field.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 8 2002

Ms. Trude C. Naff
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K012938
Trade/Device Name: Smith & Nephew Image Guided Surgical Instruments for knee applications
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: November 21, 2001
Received: November 23, 2001

Dear Ms. Naff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012938

Device Name: Image Guided Surgical Instruments for Knee Applications

Indications For Use:

Image Guided Surgical Instruments for Knee Applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Image Guided Surgical Instruments for Knee Applications are indicated for any medical condition of the knee in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure such as a long bone can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.

Example procedures include, but are not limited to:

Orthopedic Procedures:

Primary Total Knee Arthroplasty

Revison Total Knee Arthroplasty

Unicompartmental Knee Replacement

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K012938